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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,013	09/30/2005	Andreas Renz	13478-00002-US	6294
23416 7590 04/27/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
MCILWAIN, ELIZABETH F				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
04/27/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,013

Applicant(s)

RENZ ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15, 17-25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) 24, 25, 29 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 15, 17-20, 31 and 32 is/are allowed.
- 6) ☒ Claim(s) 1-10, 21, 22, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 6, 8 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 11, 2009 has been entered.
2. In addition, the amendment filed January 7, 2009 has also been entered.

Claims 1, 11, 31 and 32 are currently amended.

Claims 1-10, 16, 24, 25, 29 and 30 are withdrawn.

Claims 12-14, 16 and 26 are cancelled.

Claims 1-11, 15, 17-25, 27-32 are pending.

Election/Restrictions

3. Claims 11, 15, 17-20, 31 and 32 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 1-10 are directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because these claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement with regard to claims 1-10 as set forth in the Office action mailed on October 5, 2007 is hereby withdrawn.** In view of the withdrawal of

the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Please note that claims 24 and 25 drawn to an oil, lipid or fatty acid remain withdrawn as they are drawn to a distinct product.

In addition, please note that claims 29 and 30 drawn to methods of making feed, foodstuffs, cosmetics or pharmaceuticals by incorporating the fatty acids of claims 1 or 25 also remain withdrawn, since they are not drawn to a process of using the nucleic acid of the allowed claims.

Claims 1-11, 15, 17-23, 27, 28, 31 and 32 are examined on the merits.

Claim Objections

1. Claim 8 is objected to for the recitation of a nonhuman animal as produced by the method of claim 1, given that the method of claim 1 recites “culturing and harvesting” the organism, which is not terminology typically used for most animal species.
2. Claim 6 is objected to for the recitation of “at least two double bonds in the molecule”, given that this is redundant, as a polyunsaturated fatty acid would inherently comprise at least two double bonds.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10, 21, 22, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transforming yeast with a nucleic acid at least 95% identical to SEQ ID NO: 16 or a nucleic acid encoding a protein that is at least 95% identical to SEQ ID NO: 17 to produce C18 and C20 fatty acids when the yeast is supplemented with linoleic acid or linolenic acid, does not reasonably provide enablement for any nonhuman organism transformed with the claimed sequences or for a method of transforming any organism with the claimed sequence and optionally along with any one or more of the genes recited in claims 2, 3, 18 and 19, to produce any C18, C20, C22 or C24 fatty acids, including any of those listed in claim 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
5. The claims are drawn to any nonhuman organism transformed with the claimed sequences or for a method of transforming any organism with the claimed sequence to produce C18, C20, C22 or C24 fatty acids. However, the specification only discloses transforming yeast with a nucleic acid at least 95% identical to SEQ ID NO: 16 or a nucleic acid encoding a protein that is at least 95% identical to SEQ ID NO: 17 to produce C18 and C20 fatty acids when the

yeast is supplemented with linoleic acid or linolenic acid. The specification also teaches methods for plant transformation, but no transformed plants are disclosed. No methods for transformation of any animal species with the claimed sequences are provided in the specification.

6. The introduction of genes into animal species is highly unpredictable. McCreath et al (Nature 405: 1066-1069, 2000) teach the difficulties of animal transformation and that most animal species have not been transformed (see p. 1066 and p. 1067, column 2, the paragraphs 3, 5 and 6). In addition to the uncertainty of producing viable animal transformants, the gene would have to be expressed in the animal and the appropriate fatty acid precursors would have to be available for the production of polyunsaturated fatty acids (PUFAs).
7. The specification at page 3 discusses that there are various metabolic pathways for the production of PUFAs in different organisms, and that in mammals there is an additional step of chain shortening via beta-oxidation.
8. Given the high level of unpredictability of transforming other species, particularly animals as taught by McCreath et al, with the claimed LPAAT coding sequence, wherein the sequence is expressed such that PUFAs are produced in the organism, and given the lack of working examples of other transformed species and the resulting fatty acid composition, and given the lack of guidance with regard to methods of transformation and choice of species and gene combinations to produce any given PUFA, it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

Claims 11, 15, 17-20, 31 and 32 are allowed.

Claim 23 is objected to for depending on an rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638